EGTOP/2021

EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT

Directorate B. Quality, Research & Innovation, Outreach

B.4. Organics

Expert Group for Technical Advice on Organic Production

EGTOP

Food VIII Final Report

The EGTOP adopted this technical report at the plenary meeting of 12 – 14 December 2022

About the setting up of an independent expert group for technical advice

Regulation (EU) 2018/848[1] requires that authorisation of products and substances used in organic production may only be authorised if they comply with the principles, criteria and objectives of organic production described in that Regulation. The Commission has decided that when taking decisions on these authorisations it will take account of scientific advice by a group of independent experts. For that purpose the Commission has set up the Expert Group for Technical Advice on Organic Production (EGTOP) by Commission Decision 2021/C343/03 of 4 August 2021.

EGTOP

The Group's tasks are:

(a) to assist the Commission in evaluating technical matters of organic production, including products, substances, methods and techniques that may be used in organic production, taking into account the objectives and principles laid down in Regulation (EU) 2018/848 and additional policy objectives with regard to organic production;

(b) to assist the Commission in improving existing rules and developing new rules related to Regulation (EU) 2018/848;

(c) to stimulate an exchange of experience and good practices in the field of technical issues related to organic production.

EGTOP Permanent Group

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The report of the Expert Group presents the views of the independent experts who are members of the Group. They do not necessarily reflect the views of the European Commission. The reports are published by the European Commission in their original language only.

http://ec.europa.eu/agriculture/organic/home_en

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R0848&from=EN

ACKNOWLEDGMENTS

Members of the Group are acknowledged for their valuable contribution to this technical advice.

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All declarations of interest of Permanent Group members are available at the following webpage: www.organic-farming.europa.eu

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1. EXECUTIVE SUMMARY

The Expert Group for Technical Advice on Organic Production (EGTOP) was requested to advise on the use of several substances in organic production. The Group discussed whether the use of these substances is in line with the objectives and principles of organic production and whether they should therefore be included in Annex III of Reg. (EU) 2021/1165.

With respect to food the Group recommends the following:

- Magnesium carbonate **should** be included in Annex V B as processing aid.
- Lecithin **should** be included in Annex III as a food additive in animal origin products**.**
- Potassium sodium tartrate tetrahydrate (E337) **should** be included as a food additive.
- The extension of the use of ascorbic acid (E300) **should** be included in 'meat preparations', but the EGTOP sub-group suggests a new mandate for a comprehensive assessment of the substance.

2. BACKGROUND

Several Member States have submitted dossiers under Article 16(3)(b) of Regulation (EU) 2018/848 concerning the possible amendment of Annex IIIA and Annex IIIB to Commission Implementing Regulation (EU) 2021/1165 and, in general, on their compliance with the above-mentioned legislation. Therefore, the Group is requested to prepare a report with technical advice on the matters included in terms of reference.

3. TERMS OF REFERENCE

In light of the most recent technical and scientific information available to the experts, the Group is requested to answer if the use of the below-listed substances is in line with the objectives, criteria and principles as well as the general rules laid down in Regulation (EU) 2018/848 of the European Parliament and of the Council and, hence, can be authorized to be used in organic production under the EU organic legislation.

For the preparation of its report, the Group is invited to examine technical dossiers provided to the Commission by the Member States and suggest amendments to the current lists in Annex III to the Regulation (EU) 2021/1165.

4. CONSIDERATIONS, CONCLUSIONS AND RECOMMENDATIONS

4.1. Magnesium carbonate E504

Introduction, scope of this report

1. The request of the French authority from December 15th 2020 refers to the possible use of magnesium carbonates (E504) as processing aid (Annex V B) for the production of organic chicory powder.
2. It contains two applications:

   - E504(i): Magnesium Carbonate as food additive as drying agent / anti-caking agent;

   - E504(ii): Magnesium Hydroxide Carbonate as Processing aid for processing dried organic foodstuffs into powder, particularly for the processing of instant organic chicory.

Magnesium carbonates (E504) are currently authorised in Annex V A part 1 as additive for plant products without restriction. E504 is not authorised in Annex V A part 2 as processing aid.

Based on the existing authorisation of E504 as a food additive in Reg (EU) 2021/1165 Annex VA part 1, the evaluation is focused on the request of the French authority to add E504 as processing aid in Annex V part 2 of the same Regulation.

Authorisation in general food processing

Magnesium carbonates are authorised as food additive (E504) in Regulation (EC) No 1333/2008, generally categorized in group I "quantum satis".

The use of E504 is permitted in 'chicory extract', 'soluble chicory' or 'instant chicory': the concentrated product obtained by extraction from roasted chicory, using only water as the medium of extraction and excluding any process of hydrolysis involving the addition of an acid or a base. The chicory-based dry matter content must comply with the provisions of Directive 1999/4/EC. Chicory extract in solid or paste form may contain no more than 1% by weight of substances not derived from chicory.

Agronomic use, technological or physiological functionality for the intended use

Magnesium carbonate is, in general, used as an acidity regulator, release agent and carrier. In addition, it is used in food supplements as a source of minerals and naturally occurs in natural mineral water.

Authorisation in general production and in organic production

Magnesium carbonate is authorised in Annex III Part A (1) of Reg. (EU) No 2021/1165 for use as feed material of mineral origin.

Authorised fertilisers, soil conditioners and nutrients referred to in point (b) of Article 24(1) of Regulation (EU) 2018/848 Annex II only in natural origin e.g., magnesian chalk, ground magnesium, limestone.

Magnesium carbonate is authorised in Annex V Part A (1) (EC) No 2021/1165 for use as food additive products of plant origin without any restriction.

Agronomic use, technological or physiological functionality for the intended use

As processing aid: E504 is used to process liquid chicory into soluble powder.

The use of E504 as a processing aid in the production of soluble chicory extract improves the fluidity and, therefore, the flow of the powder.

In addition, Magnesium carbonate is added to chicory powder as an additive and an anti-caking agent to prevent the caking of the carriers due to the absorption of water.

Necessity for intended use, known alternatives

The use of an anti-caking agent or processing aid for the production of chicory powder is to be considered essential: E504 as a processing aid in producing of soluble chicory extract improves the fluidity and, therefore, the flow of the powder. Favoured flow generates a reduction in fouling in production and packaging facilities and consequently, the production becomes compatible with industrial requirements (reduction of material losses and rationalization of cleaning and the associated quantity of water).

The Group also questioned the categorization of Magnesium carbonate during processing of liquid chicory into soluble powder (processing aid or additive): based on the definition in Regulation (EC) No 1333/2008 Article 3 2 (b) it fullfils the definition of processing aid referring to:

(i)it is not consumed as a food by itself
(ii) it is intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment and processing; and
(iii) may result in the unintentional but technically unavoidable presence in the final product of residues of the substance or its derivatives, provided they do not present any health risk and do not have any technological effect on the final product.

An alternative processing aid is Calcium carbonate (E170): its technological use is comparable with magnesium carbonate. Calcium carbonate is listed in Annex V section A 2 processing aids commission implementing regulation (EU) 2021/1165 products of plant origin.

It was argued that Calcium and Magnesium carbonates, both bioavailable forms of calcium and magnesium, proportion may have a role in final food formulation decision.

Another alternative is Silicon dioxide (E551): that - gel or colloidal solution - is listed in Annex V section A 2 processing aids commission implementing regulation (EU) 2021/1165 products of plant origin.

Origin of raw materials, methods of manufacture

Magnesium carbonate occurs naturally in drinking and mineral water as "hardness", in rocks mostly as a companion of calcium, and in seawater at an average concentration of 1.4g/l Mg. Pure magnesium carbonate is extracted from dolomite (magnesium & calcium carbonate) by the Pattinson process. (Ref:http://www.mercury-emmissions.com/brome/brome.nsf/viewAllByUNID/6BE203A282A84F44C22570C800315201/$file/The_Pattinson_Process.pdf)

Environmental issues, use of resources, recycling.

No significant environmental issues caused by Magnesium carbonate are known. It is widely available in various forms, and its use is not reported to cause any concerns. The disposal of small amounts of Magnesium carbonate would not be expected to create any environmental concerns. High concentrations of Magnesium in the water contribute to water hardness which has been associated with cardiovascular disease, but the contribution of Magnesium carbonate in organic food would be minor in this respect.

Animal welfare issues

No specific concerns.

Human health issues

The Joint Food Agriculture Organisation and World Health Organisation (FAO/WHO) experts Committee on Food Additives estimated that acceptable daily intake of magnesium carbonate for man is not limited (17th Report of the Joint FAO/WHO Expert Committee on Food Additives, Wld Hlth Org. techn. Rep. Ser., 1974, No. 539; FAO Nutrition Meetings Report Series, 1974, No. 53).

The milling of magnesium carbonate will result in creation of some nanoparticles: most will agglomerate after production, but some may be left (Kohlhuber, 2010). On the basis of presently available information, there is no indication of health concerns: the Group further analyzed the issue, as it is critical to the evaluation outcome.

Although EFSA opinion on the safety of magnesium carbonate as a food additive is not available yet, a call for data was published in 2012, including a request for information on particle size and particle size distribution. However, EFSA identified a nano-fraction on calcium carbonate when they evaluated their safety as a food additive (E170) in 2011 and nevertheless positively concluded on the safety of this carbonate, pending further information becomes available. In addition, both Reg. (EC) No 1170/2009 and Reg. (EU) No 609/2013 included magnesium carbonate as a permitted source of magnesium. In conclusion, this shows that, even in the presence of a nano-fraction, the product is deemed as safe, also considering that it is duly included as a permitted source of magnesium.

Food quality and authenticity

In the production of chicory powder, the drying methods used maintain the characteristics and qualities of the product. The use of magnesium carbonate as an anti-cacking agent has to be declared in the ingredients list, granting due transparency/authenticity.

Article 7 b of Reg. (EU) 2018/848 mentions: the restriction of the use of food additives, of non-organic ingredients with mainly technological and sensory functions, and micronutrients and processing aids, so that they are used to a minimum extent and only in cases of essential technological need or for particular nutritional purposes is not touched.

Referring Article 24 4 8(a)2018/848, the requirements are fulfilled as follows:

- the use of magnesium carbonate is in accordance with the regulation (EC) No 1333/2008;
- the use of an anti-caking and or a processing aid for the production of chicory powder is considered essential;
- the substance is available in natural origin.

Traditional use and precedents in organic production

As previously reported, it has been allowed in organic farming as fertilizer, feed additive, and food additive for decades.

Authorised use in organic farming outside the EU / international harmonisation of organic farming standards

In the NOP (National Organic Program NOP 7 CFR 205.105(c)) the use Magnesium carbonate is prohibited.

https://www.omri.org/omri-search?page=1&query=magnesium%20carbonate&exactMatch=false&rulingbodies=nop&classes=pa,pn

According to the Codex Alimentarius Commission "Guidelines for the production, processing, labelling and marketing of organically produced foods Annex 2: Permitted substances for the production of organic foods": Magnesium carbonate is permitted in food of plant origin.

It is permitted as an additive in Japanese Organic Standards (JAS), as an additive and post-harvest treatment with the condition: Limited to be used for processed foods of plant origin.
Finally, it is permitted in IFOAM Norms for Organic Production and Processing. Appendix 4 – Table 1: List of approved additives & processing /post-harvest handling aids as an additive, without restrictions.

Other relevant issues

None.

Reflections and Conclusions

Magnesium carbonate as such is evaluated as unproblematic. An amendment in the use as food additive for E504 i is not needed because this is covered by the general acceptance of E504 as food additive in EU Reg.2021/1165.
The request for inclusion as processing aid led to the following reflections:

1. as an alternative, calcium carbonate is allowed and the dossier does not explain why such alternative is not considered, while there is clear reference to silicon dioxide replacement. Silicon dioxide (E551) is allowed as food additive in Annex V A 2021/1165 for herbs and spices in dried powdered form, flavourings and propolis, while it is allowed in gel or colloidal solution for products of plant origin as processing aid. Based on the natural occurrence of nano particles and their case-by-case evaluation from the scientific panel of EFSA, the use of magnesium carbonates (E504) as processing aid is currently considered as preferrable to the use of silicon dioxide.
2. The use of E504 as a processing aid in the production of soluble chicory extract improves the fluidity and therefore the flow of the powder. It was discussed if this use is correctly categorized as processing aid or it is more appropriate to name it as food additive. Referring to the definition of processing aid, it was questioned if the magnesium carbonate keeps active in the final product as an anti cacking agent in the chicory powder. Especially considering that traces of magnesium carbonate remain in the final product and, secondly, magnesium carbonate is described to be applied during the drying process. So, the magnesium carbonate will remain in the final product. Based on the definition in (EC) Reg. 1333/2008. The Group came finally to the conclusion that the use of magnesium carbonate, used at levels necessary to achieve the desired technological effect, should be allowed.

3. A final concern pertains the potential restriction of the origin of magnesium carbonate as food additive or processing aid (natural origin, e.g. magnesian chalk, ground magnesium) that could be taken into consideration to grant consistency with Authorised fertilisers, soil conditioners and nutrients referred to in point (b) of Article 24(1) of Regulation (EU) 2018/848 Annex II which demands natural origin of E 504. The Group concluded that the topic could be topic fur future discussion but it is not in the present scope.

The group concludes that the use of Magnesium carbonates (E504 i and ii) as processing aid is in line with the objectives, criteria and principles of Council Regulation (EC) No 848/2018.

Nevertheless, the specific use in chicory powder described in the application, does not sufficiently explain if its use is to be understood as processing aid or as a food additive, therefor EGTOP' recommendation is based on the assumption that France has made a correct legal interpretation of the definition in Regulation (EC). 1333/2008

Recommendations

The group recommends Magnesium carbonates to be included in Annex V A part 2 of EU Reg. 2021/1165.

E504	magnesium carbonates	food processing aid[2]	

References

- COMMISSION REGULATION (EC) No 1170/2009 of 30 November 2009 amending Directive 2002/46/EC of the European Parliament and of Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements.
- REGULATION (EU) No 609/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009.
- 17th Report of the Joint FAO/WHO Expert Committee on Food Additives, Wld Hlth Org. techn. Rep. Ser., 1974, No. 539; FAO Nutrition Meetings Report Series, 1974, No. 53.
- Kohlhuber M., 2010. Lebensmittel und Nanotechnologie, Neues Forschungsprojket des Bayer. LGL und des Frauenhofer IVV" Deutsches Zentrum für Luft- und Raumfahrt e. V. (DLR), Köln.

4.2. Lecithin, extension of use

Introduction, scope of this report

The 2021 request of the Swedish authority refers to the possible use of Lecithin (E322) as a food additive of organic quality to be used in animal-origin products.

Lecithin (E322), based on the existing Reg (EU) 2021/1165, is currently authorised:

- as a feed additive (emulsifier) use restricted for aquaculture feed;
- as a food additive (emulsifier), only of organic origin, use restricted to all plant based products and milk products;
- as basic substance, in plant protection.

Authorisation in general production and in organic production

Lecithins E322 (also includes lecithin partially hydrolysed) are authorised in many food categories including animal products. Lecithins do not have a numerical ADI (ADI "not specified") and are authorised in most applications in *quantum satis*.

Lecithins are included in Group I of food additives and as such are authorised in *quantum satis* in a long list of categories (https://webgate.ec.europa.eu/foods_system/main/index.cfm?event=substance.view&identifier=1), including:

1. Non-heat-treated processed meat (8.3.1) (legislation: (EU) No 1129/2011, applicable as from 01/06/2013)
2. Casings and coatings and decorations for meat (8.3.3) (legislation: (EU) No 1129/2011, applicable as from 01/06/2013)
3. Heat-treated processed meat (8.3.2) (legislation: (EU) No 1129/2011, applicable as from 01/06/2013)

[2] Provided that France correctly categorised the use as processing aid.

In addition to Group I authorisations, lecithins are also authorised in the following categories (in *quantum satis* or with maximum level for certain food categories *e.g.*, infant formulae): https://webgate.ec.europa.eu/foods_system/main/index.cfm?event=substance.view&identifier=115

Concerning organic production, Lecithin is currently authorized by Regulation (EU) 2021/1165, as reported in the following Annexes:

1. *ANNEX I part 1 (Active substances contained in plant protection products authorised for use in organic production as referred to in point (a) of Article 24(1) of Regulation (EU) 2018/848) as basic substance for plant protection. Organic origin not compulsory, but not containg or deriving from GMO;*
2. *ANNEX III, part B (Authorised feed additives and processing aids used in animal nutrition referred to in point (d) of Article 24(1) of Regulation (EU) 2018/848 - as an emulsifier: only when derived from organic raw material, use restricted to aquaculture animal feed);*
3. *ANNEX V, part A (Authorised food additives and processing aids referred to in point (a) of Article 24(2) of Regulation (EU) 2018/848, as an emulsifier, only from organic production. Use restricted as additive for all plant based products and for animal products restricted to Milk products.*

Agronomic use, technological or physiological functionality for the intended use

According to Regulation (EC) 1333/2008 on food additives:

1. *a food additive may be included in the Community lists in Annexes II and III only if it meets the following conditions and, where relevant, other legitimate factors, including environmental factors:*
2. *on the basis of the scientific evidence available, it does not pose a safety concern to the health of the consumer at the level of use proposed;*
3. *there is a reasonable technological need that cannot be achieved by other economically and technologically practicable means;*
4. *its use does not mislead the consumer.*

Functional classes are defined in Annex I of the afore-mentioned Regulation, among which the class of emulsifiers: '*emulsifiers' are substances which make it possible to form or maintain a homogenous mixture of two or more immiscible phases such as oil and water in a foodstuff*.

Lecithin has been used in food production for many years: it is used wherever the emulsifying and dispersing properties of the substance offer advantages. Its use can replace synthetic emulsifiers (i.e. for the production of baked goods, chocolate and confectionery, instant products like various drinks including protein and milk shakes, vegetarian products and meat broths/sauces).

The request from Sweden focuses on the use of lecithin of organic quality for production of instant protein powder of animal origin, however, the application is wider and quotes "*Approval of organic Lecithin (E322) as an additive to animal products*".

For the quoted production of instant protein powder of organic animal origin, lecithin of organic quality is sprayed on a protein powder (at a dosage of 0.2 – 1.0 %) to allow the powder to dissolve instantaneously.

Necessity for intended use, known alternatives

According to the dossier, for manufacturers seeking the functionality lecithin offers, there are no known suitable alternatives approved for organic production. Freeze-dried process was considered a potential and preferred alternative, but concerns emerged over its high energy requirements.

Origin of raw materials, methods of manufacture

For the current request, the origin of raw materials and methods of manufacture is not relevant as its origin is restricted to organic production. Details of the process can be found at the EGTOP report Food II.

Environmental issues, use of resources, recycling.

The example of use quoted by the applicant is meant to produce instant protein power starting from animal co-products with low economic value (meaty bones and hide/skin which would otherwise be discarded). So doing, it contributes to an improved use of animal co-products, maximization of resource uses, and minimization of waste streams. Similarly, the emulsifying properties of organic lecithines would unlock the manufacture of other organic food products of animal origin for which currently there is no market request at the food retail level (promoting circular economy also in organic).

Animal welfare issues

Not applicable.

Human health issues

Lecithins (E322) were re-evaluated in 2017 by the former EFSA Panel on Food Additives and Nutrient sources added to Food (ANS). As a follow-up to that assessment, the Panel on Food Additives and Flavourings (FAF) was requested to address the issues identified during the re-evaluation of the food additive (E322). The Panel concluded that the intake of lecithins (E322) as a food additive in infant formula belonging to FC 13.1.1 or in food for special medical purposes belonging to FC 13.1.5.1 does not raise safety concerns up to the maximum permitted level (MPL) of lecithins (E322).

Food quality and authenticity

The group discussed possible issues related to food authenticity. Reference was made to this text of organic law (Reg. (EU) 2018/848):

Products, substances and techniques that reconstitute properties that are lost in the processing and storage of organic food, that correct the results of negligence in the processing of organic food, or that otherwise may be misleading as to the true nature of products intended to be marketed as organic food, shall not be used.

The legal definition of emulsifiers functional class, for which lecithin is authorised in the EU -Regulation (EC) 1333/2008-, was recalled: *'emulsifiers' are substances which make it possible to form or maintain a homogenous mixture of two or more immiscible phases such as oil and water in a foodstuff.*

The group agreed on the appropriateness of recalling authorised possible uses in the EGTOP report.

Traditional use and precedents in organic production

Lecithins of conventional, non GM origin, has been authorized in organic since decades ad food and feed additive and also as plant protection product (annex I). Since 2019, its use as food additive has been restricted to organic lecithin and its availability is nowadays granted.

For other uses (plant protection) also conventional lecithins can be used, providing they are not of GM origin.

Authorised use in organic farming outside the EU / international harmonisation of organic farming standards

In the U.S., de-oiled (free of oil) lecithin is also permitted (https://www.ams.usda.gov/rules-regulations/national-list-allowed-and-prohibited-substances) in foods marketed as organic. In BioSuisse

standards organic lecithin is allowed for use in baby food, as an ingredient in anticaking agents for bakery products, and to produce marine and grace margarine, coated yeast, and chocolate powder (but not for chocolate).

Other relevant issues

None.

Reflections and Conclusions

The group discussed on the appropriateness of meeting the Swedish request of aligning for lecithins of organic quality the possible uses. Some concerns emerged over the possible use of lecithins for "reconstitution" of food of animal origin. The group concluded that, given the whole EU legal framework, the risk is considered under control and Regulation (EU) 1169/2011 was recalled:

Meat products, meat preparations and fishery products which may give the impression that they are made of a whole piece of meat or fish, but actually consist of different pieces combined together by other ingredients, including food additives and food enzymes or by other means, shall bear the following indication: 'formed meat' and 'formed fish'.

The Group concluded that the use of organic Lecithin as an additive for animal products is in line with the objectives, criteria and principles of Council Regulation (EC) No 848/2018.

Recommendations

The group recommends the addition of "animal products" in the description of "Organic foodstuffs to which it may be added" besides Lecithin as additive into Annex V Part A - A1 of Regulation 1165/2021.

E322*	Lecithins	products of plant origin products of animal origin milk products	Only from organic production

The Group also recommends reviewing and harmonizing the use of organic lecithins (***versus conventional*** non GM, derived from organic raw material) for the other uses (feed additive and plant protection substance).

References

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- Final Report On Food (II) 2014. Expert Group for Technical Advice on Organic Production EGTOP EUROPEAN COMMISSION DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT

4.3. K-Na-Tartrat Tetrahydrat (E337)

Introduction, scope of this report

The request pertains to the inclusion of "Potassium sodium tartrate tetrahydrate" (E337)[3] as acidity regulator for jellies, jams, marmalades, and sweets and also as backing powder. The dossier was prepared by the German organic processors association AöL and presented by the German authority.

Authorisation in general production and in organic production

Potassium Sodium tartrate, $KNaC_4H_4O_6$, also known as "Rochelle salt" was prepared for the first time in 1675 and was/is well known for its piezoelectricity proprieties. It is allowed in EU as food additive (EU Regulation No. 1333/2008) and EFSA in 2020 reassessed it, together with other tartrate salts, expressing the following opinion[4] "The Panel established a group ADI for l(+)-tartaric acid-tartrates (E334-337 and E 354) of 240 mg/kg bw per day" and expressed as well some recommendations "Revising the EU specifications for monosodium tartrate (E335), disodium tartrate (E335, monopotassium tartrate (E336), dipotassium tartrate (E336) and potassium sodium tartrate (E337) in order to introduce a provision for specific rotation to ensure the exclusive use of the authorised L(+)-stereoisomer in these food additives."

As an additive in food industry, it acts as a sequestrant, emulsifier, stabilizer, buffer, and antioxidant in cheese products, margarine, jellies, jams, minced meat, and sausage casings.

In pharmacology, it is used as saline cathartics; it is not to be used on persons with heart problems or those on low-sodium diets. Potassium Sodium Tartrate is also used to remove toxic materials in some cases of poisoning.

Other applications include the preparation of piezoelectric crystals used in electrical appliances; in the manufacture of mirrors; in the plating industry; as a laboratory reagent; in the preparation of Fehlings solution for the detection of aldehydes; and for delaying the quick-setting of gypsum.

In organic production it is not authorized for any use, while sodium tartrate (E335) and potassium tartrate (E336) are listed in annex V part A of Reg.CE 2021/1165 for use only in products of plant origin. Besides, tartaric acid (E334) is allowed for use in plant-origin products and mead. In part D of the same regulation, additives for winemaking, the following forms are listed: tartaric acid (334), potassium tartrate (E336), metatartaric acid (E353), and potassium hydrogen tartrate (E366).

Agronomic use, technological or physiological functionality for the intended use

The purpose of the use of sodium potassium tartrate tetrahydrate is acidity regulator in plant-based products (such as jams) and as backing powder, as for the other tartrate salts already authorized. In addition, the report claims that the substance E337 is relevant for recipes with pectin, as a buffer salt is needed for fruit preparations in baked goods and sour milk products in order to control the pH value during the production.but the request does not include the use in animal products). The request highlights that the present regulatory framework allows the use of both salts forming E337 separately and it may sound irrational not to allow the double salt *per se*, that would avoid a purification step. Nevertheless, the dossier describes E337 as a wine industry by-product, while it is not exactly so, as reported in the paragraph on origin of raw material, methods of manufacture.

Necessity for intended use, known alternatives

[3] The request was for use as processing aid, but other tartrates are authorised as food additives in FC 4.2.5.1 Extra jam and extra jelly as defined by Directive 2001/113/EC

[4] https://www.efsa.europa.eu/en/efsajournal/pub/6030

For the same scope, the EU regulation on organic farming offers several alternatives, among them, the other tartrate salts.

Origin of raw materials, methods of manufacture

The starting material is potassium bitartrate with a minimum tartaric acid content of 68%. This is first dissolved in water or the mother liquor of a previous batch; then, it is basified with a hot saturated sodium hydroxide solution to pH 8, decolorized with activated charcoal, and chemically purified before being filtered. The filtrate is evaporated to 42°Bé at 100 °C, and passed to granulators where Seignette's salt crystallizes on slow cooling. The salt is separated from the mother liquor by centrifugation, accompanied by the washing the granules, and is dried in a rotary furnace and sieved before packaging. Commercially marketed grain sizes range from 2000 μm to < 250 μm (powder).

The dossier reports E337 as wine-making by-product, but what naturally comes from the wine-making process is only potassium bitrartrate (or "potassium hydrogen tartrate", potentially with minimal traces of sodium). As a matter of fact, grape contains tartaric acid that is transformed into potassium bitartrate during fermentation: no sodium potassium tartrate is formed in wine-making. Instead, what is naturally produced during wine aging is potassium-bitartrate, that can be dried, purified and ground and put on the market as a leavening agent (baking powder), but it does not have the jellifying effect required in jams and similia or as a cleaning solution (when mixed with an acidic solution such as lemon juice or white vinegar).

Environmental issues, use of resources, recycling.

E337 is not radically different from other tartrate salts, even if its production requires extra steps of simple chemistry. If the tartrate comes from the wine industry and is not of synthetic origin, it can contribute to circular economy and waste reduction. Considering the size of organic wine-making in Europe and the fact that the extraction of tartrate from pomace is a batch (discontinuous) and simple process, there can be space for the organic production of tartrate.

Animal welfare issues

Not applicable.

Human health issues

See EFSA reassessment (EFSA, 2020).

Food quality and authenticity

Its action is analogous to other tartrate salts, as a consequence, it seems not to hamper the quality nor the authenticity of the products where it is used.

Traditional use and precedents in organic production

Tatrate salt (potassium) have been used in organic processing as baking powder and as an acidifier for decades, allowed in IFOAM basic standards. On the contrary, E337 has never been allowed.

Authorised use in organic farming outside the EU / international harmonisation of organic farming standards

In paragraph 205.605, the NOP allows various modifications of tartaric acid for use in organic food: tartaric acid is allowed in the form of potassium acid tartrate and potassium tartrate, but there is no mention of E337.

Bio Suisse standards allowed E335 and E336 for jelly and gum sugar goods and as backing powder, but not E337.

Other relevant issues

None.

Reflections and conclusions

The group discussed the need for E337 to be added, on potential differences from other tartrate salts already allowed in organic and the opportunity to introduce the request for all tartrate salts to be organic, as the production process and the availability of raw material would allow so.

Besides, the Group highlights that the dossier does not clearly states if the request pertains only products of plant origin or also milk.

Recommendations

The Group recommends the inclusion of Potassium Sodium Tartrate (E337) as a food additive in Annex V part A, Section A1 of Reg. (EU) 2021/1165

Besides, the Group supports the need to allow in the time-frame of three years the use tartrate salts, only if they come from certified organic production.

E335	Sodium tartrates	Products of plant origin	from 2027 on: only from organic production
E336	Potassium tartrates	Products of plant origin	from 2027 on: only from organic production
E337	Potassium sodium tartrate	Products of plant origin	from 2027 on: only from organic production

References

- Re-evaluation of l(+)-tartaric acid (E334), sodium tartrates (E335), potassium tartrates (E336), potassium sodium tartrate (E337) and calcium tartrate (E354) as food additives. EFSA Journal 2020;18(3):6030 DOI: https://doi.org/10.2903/j.efsa.2020.6030.

4.4. Ascorbic acid, extension of use

Introduction, scope of this chapter

The request relates to the extension of the use of ascorbic acid (E300) to organic 'meat preparations'. This substance is already included in Reg. (EU) No. 2021/1165, Annex V Part A Section A1 – Food Additives, including Carrier, it may be added to products of plant origin and meat products. The dossier was submitted by the Belgian Authority.

Authorization in general production and in organic production

Ascorbic acid is authorized by Council Regulation (EU) No 231/2012 regarding food additives & specifically in Regulation (EC) No 1333/2008.

Regulation (EC) 853/2004 defines meat preparations in its Annex I: "*fresh meat, including meat that has been reduced to fragments, which has had foodstuffs, seasonings or additives added to it or which*

has undergone processes insufficient to modify the internal muscle fibre structure of the meat and thus to eliminate the characteristics of fresh meat". In addition, Regulation (EC) 1133/2008 on food additives and its amending Regulation (EU) 1129/2011 (amending Annex II by establishing a Union list of food additives) specify all the authorized uses. In this regulation E300 is included in Group I, as food additive, and is authorized for meat preparations, as defined in Regulation (EC) 853/2004 (category 8.2), with the following restrictions/exceptions: "*quantum satis, only gehakt and prepacked preparations of fresh minced meat*".

Agronomic use, technological or physiological functionality for the intended use

Ascorbic acid occurs naturally in many fresh fruits and vegetables, from citrus fruits and grapefruits to broccoli, Brussel sprouts and tomatoes: in these foods, however, vitamin content can be reduced by heat, boiling water, or air.

E300 is a reducing agent, as it tends to oxidise in the presence of oxygen and form dehydroascorbic acid. Its reducing properties prevent oxidation, which is responsible for discoloring in meat during storage, and the formation of metamyoglobin. Moreover, the lipids oxidation may be delayed because the addition of ascorbic acid and consequent oxidation of this additive reduce the oxygen available for lipids breakdown. The addition of ascorbic acid improves meat color and shelf life.

Ascorbic acid, is also known as vitamin C; however, when used as an antioxidant, it cannot be classed as vitamin C.

Necessity for intended use, known alternatives

According to the dossier, there are no available alternatives.

However, E306 (Tocopherol - rich extract) is already authorised for products of plant and animal origin as an antioxidant (Regulation (EU) No. 2021/1165 Annex V, Part A, Section A1). The organic food sector should be encouraged to produce tocopherol-rich extract in certified organic form from organically grown agricultural ingredients.

Acerola fruit powder, a rich source of ascorbic acid, is a used organic alternative and is mandatory within the standards of some private Organic labelling organisations like Demeter and Bio Suisse.

Origin of raw materials, methods of manufacture

According to the dossier, the ascorbic acid comes mainly from China but there is no information regarding the manufacturing method. It is estimated that manufacturers in China produce up to 95% of the vitamins used for supplementation and enrichment, however, China's booming manufacturing industry has seen it produce more carbon emissions than any other Country in the World. So, back in 2013, the China Clean Air Action Plan was launched to cut carbon emissions and reduce air pollution, by early 2018, the development and implementation of this plan resulted in the shutdown of any production facilities that didn't meet certain criteria on emissions. This had a knock-on effect on the production of ascorbic acid in China, impacting supply worldwide. However, the manufacture upgrades have delivered significant reductions in its environmental footprint and improved quality, safety, and production efficiencies. That means that there are more sustainable options on the market today.

However, earlier times ascorbic acid has been commercially produced by extracting it from plants. This is considered the most natural method of production. In more recent years, ascorbic acid was chemically synthesized. Presently it is produced by two processes: a) the Reichstein process, a seven steps combination of synthesis and microbial conversion. This process is used to produce the majority of commercial ascorbic acid; b) the alternative is the more recently developed double fermentation process.

According to the dossier, the production process does not involve GMOs, but it is not known if the statement is related to the process of fermentation or just because it is chemically synthetized.

Environmental issues, use of resources, recycling.

No information provided in the dossier.

However, if chemical synthesis is used, although the Reichstein process has all the efficiency advantages that would be expected after more than 60 years of development, it is still highly energy consuming and requires high temperatures and/or pressures for many steps. In addition, most of the chemical transformations involve considerable quantities of organic and inorganic solvents and reagents such as acetone, sulfuric acid, and sodium hydroxide. Although some of the compounds can be recycled, stringent environmental control is required, resulting in significant waste disposal costs.

The use of solvents and precipitation processes during the isolation and purification includes strong acids and alkalis, which cause concern.

Animal welfare issues

None identified or expected, because E300 is not for animal application and not produced by animals, but the production process specifically used is not specified, so the potential release of impacting substances is not known.

Human health issues

E300 is authorized as "*quantum satis*".

Food quality and authenticity

Ascorbic acid should be used in accordance with good manufacturing practice, at a level not higher than what is necessary to achieve the intended purpose and provided the consumer is not misled.

Traditional use and precedents in organic production

As traditional use: preservative and antioxidant in meat preparations[5] (minced meat, meat balls, hamburger, sausage, chipolata).

Authorized use in organic farming outside the EU / international harmonization of organic farming standards

No information was found in the dossier.

However, without restriction, ascorbic acid is permitted under USDA National Organic Programme §205.605 b Synthetics Allowed. In Japanese Organic Standards (JAS), Ascorbic Acid is permitted as an additive with the following condition: limited to be used for processed foods of plant origin.

In IFOAM Norms for Organic Production and Processing. Appendix 4 – Table 1: List of approved additives & processing /post-harvest handling aids as an additive without restrictions.

Other relevant issues

None

Reflections and conclusions

The Group claims that not enough data regarding the environmental issues were supplied and are not available in the literature.

[5] E300 is authorised in category 8.2 as follows: only gehakt, prepacked preparations of fresh minced meat and meat preparations to which other ingredients than additives or salt have been added

After considering that the substance is already authorized in organic for ‘meat products’ (Regulation (EU) No. 2021/1165, Annex V Part A Section A1), the Group recommends the extension of the use of ascorbic acid to organic ‘meat preparations’, considering fair treatment as for "meat products". Meanwhile, synthetic forms of the substance should only be used if organic and natural sources are not available.

However, the Group noted i) the legal framework has changed since the first authorization, ii) the production process poses some concerns, such as the energy cost and the possible use of GMOs, iii) alternatives are potentially available, more in line with the new provisions on organic farming. Therefore, the Panel suggests a new mandate for a comprehensive assessment.

Finally, in the evaluation, it becomes evident that in some translations of the Regulation (EU) 2021/1165, when it comes on authorized uses, the meaning associated to the wording used for specifying meat products differs (de-facto including already meat preparations): that is the case of the German translation. The group recommends verifying and taking it into account by the adoption of the legislation.

Recommendations

The Group recommends adding “meat preparations” in the “organic foodstuff to which it may be added” besides Ascorbic acid in Annex V Part A Section A1 of Reg. (EU) 2021/1165.

E300	Ascorbic acid	products of plant origin meat products and preparations to which other ingredients than additives or salt have been added	

Due to the new regulatory framework and alternatives becoming available, the group also recommends a new mandate for a whole reassessment of ascorbic acid use in organic farming.

The group also recommend a check of the translation in the different languages of the annex V.

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5. MINORITY OPINION

None.